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Docket No. X-16038

### Remarks

Claims 1-4 are in the present patent application. Applicants have amended page 3 by deleting the last sentence of paragraph 2; "The above compound has been selected for having a surprisingly superior toxicology profile over the compounds specifically disclosed in application cited above" pursuant to a telephone conversation on June 19, 2006 with the Examiner. Applicants have amended Claim 2 to remove "and the pharmaceutically acceptable salts thereof". Applicants kindly request entry of the proposed amendments to the specification and to Claim 2.

Applicants request reconsideration and allowance of Claims 1-4 in view of the following arguments.

### Rejection of Claims 1-4 under Obviousness-Type Double Patenting

Claims 1-4 stand rejected for obviousness-type double patenting over Claims 1-2 and 389 of United States Patent Application No. 10/477,111, now allowed. The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct. Applicants respectfully traverse the present rejection.

A double patenting rejection of the obvious-type is analogous to the nonobviousness requirement of 35 USC 103 except that the patent principally underlying the rejection is not considered prior art. (MPEP 804 II.B.1., citing *In re Braithwaite*, 379 F.2d 594 (CCPA 1967)). Since the analysis employed in an obvious-type double patenting rejection parallels the guidelines for a 103 rejection, the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1 (1966) are applied. These include; (a) determining the scope and content of the patent claim and the prior art relative to a claim in the application at issue, and (b) determining the differences between the scope and content of the patent claim and the claim in the application at issue. (MPEP 804 II.B.1)

Here, rather than considering the full scope and content of the conflicting patent claims and setting forth why one of skill in the art would conclude that the present invention is but an obvious variation, the Examiner simply notes that the instant claims are fully embraced by the Markush claimed in the allowed claims. However, Applicants respectfully submit that the mere existence of an earlier filed Markush – later filed species relationship is an insufficient basis upon which to conclude non-statutory double patenting exists.

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As noted, the present application claims a species which represents a narrower embodiment of the genus claimed in United States Patent Application No. 10/477,111. In other words, the present invention represents a "selection" invention which is said to be "dominated" by the earlier filed patent. However, domination and double patenting should not be confused. They are separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds cannot support a double patenting rejection. MPEP 804 II (citing *In Re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986)).

The Examiner has not presented any grounds for the present rejection other than the mere existence of a Markush – species relationship between the cited claims of United States Patent Application No. 10/477,111 and the claims at issue in the present application. Furthermore, applying the factual inquiries as set forth in *Graham*, it is clear that the present invention is drawn to a nonobvious and patentably distinct invention. The cited Claims (1-2 and 389) of the United States Patent Application No. 10/477,111 each encompass a broad genus of chemical agents. The claims at issue in the present application, however, are narrowly drawn to the particular species defined by Formula II therein. Without more, one of ordinary skill in the art would have no motivation to select the precise species of the present invention simply in view of the cited claims of United States Patent Application No. 10/477,111.

For the foregoing reasons, Applicants assert that the Examiner has failed to make the case to support an obvious-type double patenting rejection and ask that the provisional rejection be withdrawn.

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If the Examiner has any questions, or would like to discuss any matters in connection with this application, she is invited to contact the undersigned at (317) 277-3537.

Respectfully submitted,



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